UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION _____ **THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE ANNE M. WEBER, M.D.

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") request that the testimony of Anne M. Weber, M.D. be excluded in its entirety.

I. INTRODUCTION

Dr. Weber was a practicing gynecologist and surgeon until 2005. Today, she is a professional expert witness for pelvic mesh plaintiffs. Dr. Weber is designated as an expert in two Prolift cases, listed in Exhibit A.

The Court should exclude Dr. Weber's opinions in their entirety.

First, Dr. Weber is not qualified to testify about the primary subjects of her expert report. Dr. Weber does not have any direct experience with the Prolift device. She stopped performing surgeries before Ethicon began marketing the device. She has not undertaken any continuing medical education on the subject. She has not practiced medicine in more than a decade. Nor is she qualified to testify about medical device design, development, and testing, or biomaterials and polymer science.

Second, if permitted to testify at all, Dr. Weber should be precluded from offering unreliable and irrelevant testimony concerning:

- Biomaterials or the Prolift design;
- Ethicon's premarket testing or study of Prolift;
- The Johnson & Johnson Credo;
- Ethicon's knowledge or intent;
- The informed consent process for study participants;
- Ethicon's handling of issue reports;
- The selection of physicians for training;
- Summaries of documents and evidence; or
- Unscientific and inflammatory language.

These opinions are inadmissible under the Federal Rules of Evidence and should be excluded.

II. BACKGROUND

A. Dr. Weber's Background.

Dr. Weber is a former practicing physician and surgeon. She discontinued practicing medicine in 2005 and surrendered her medical license in 2007. *See* Ex. B, 11/5/12 Weber Dep. at 28:4-18, 146:17-20. Dr. Weber has not performed any surgery since 2004—the year before Ethicon launched Prolift. *See id.* at 27:24-28:3. It has been a decade since Dr. Weber last saw a patient. *See id* at 28:4-18. Since surrendering her medical license, Dr. Weber has not attended any continuing medical education courses. *See id.* at 146:21-23.

Dr. Weber had no experience with Prolift during the time she practiced medicine. She never used or implanted Prolift. *See id.* at 69:14-16. She never participated in any professional education regarding Prolift or any other pelvic mesh products. *See id.* at 175:14-17. Likewise, she never spoke with any Ethicon sales representatives or proctors about Prolift. *See id.* at 175:22-25, 178:12-16. Dr. Weber also never performed any cadaver training on the use of Prolift or any other mesh products for pelvic floor repair. *See id.* at 175:18-21. In fact, she has never even witnessed the implantation of a Prolift device. *See id.* at 176:6-19.

Notably, in developing her opinions, Dr. Weber never spoke with any surgeon who has actually used Prolift or who has been trained on the use of Prolift, even though the IFU for the device specifies that it should be used only by surgeons familiar with "techniques involving pelvic floor repair and synthetic meshes." *See* Ex. C, 11/6/12 Weber Dep. at 276:8-21.

Just as Dr. Weber has no experience implanting Prolift devices, she has no experience removing the devices and extremely limited experience even treating patients with mesh complications. Dr. Weber has never examined a patient who was implanted with a Prolift device. Ex. B, 11/5/12 Weber Dep. at 185:19-24. She has never removed all or any portion of a Prolift implant. *See id.* at 185:14-18. She admits that over her entire career, she has only treated "less than five" patients for mesh erosion and has only done a mesh resection procedure one time for the TVT device, a sling mesh device which treats stress urinary incontinence. *See id.* at 187:12-17. Other than this small handful of patients, Dr. Weber does not recall treating any patient for any mesh-related complication. *See id.* at 189:22-25. Further, she admits she has never treated a patient who was experiencing mesh contraction or an infection related to the mesh. *See id.* at 189:8-16

Dr. Weber is not and has never been an employee of or a consultant to the FDA. *See id.* at 38:1-4. Nor has she ever been an employee of or a consultant to a medical device manufacture. *See id*. at 30:24-31:2, 179:16-20. She has never been involved in the design of a medical device or the safety assessment of a medical device. *See id.* at 31:14-18; Ex. D, *Gross* 1/17/13 Trial Tr. at 1307:5-12. She has never been involved in a pre-market clinical trial of a medical device. *See* Ex. B, Weber 11/5/12 Dep. at 33:4-15, 198:9-13; Ex. D, *Gross* 1/17/13 Trial Tr. at 1307:13-16. She has never prepared, assisted in the preparation of, or even reviewed a Section 510(k) application for the FDA's approval of a medical device. *See* Ex. B, Weber

11/5/12 Dep. at 31:3-13.

She is not a biomedical engineer. *See id*. at 192:2-11. She is not a polymer scientist. *See id*. at 191:25-92:2. She has never developed warnings to accompany a medical device. *See id*. at 179:21-24. She has never studied the physical characteristics of Prolift or any other transvaginal mesh. *See id*. at 190:1-93:15. Likewise, she has never engaged in a meta-analysis of the medical literature regarding transvaginal mesh in general or Prolift specifically to assess the safety and efficacy of these products. *See* Ex. C, Weber 11/6/12 Dep. at 257:11-13.

Since Dr. Weber quit the practice of medicine in 2005, her principal and almost exclusive source of earnings has come from her work as an expert witness for plaintiffs' counsel. *See* Ex. B, Weber 11/5/12 Dep. at 13-15.[1] Before the rise of the pelvic mesh litigation, Dr. Weber had only been deposed as an expert witness on one previous occasion, offering opinion testimony about the standard of care in a medical malpractice action. *See id.* at 10:10-11:7. Other than her work on that single malpractice case, all of her professional witness experience has come from opining on behalf of plaintiffs in the pelvic mesh litigation.

In her role as a professional witness, Dr. Weber has engaged in numerous "firsts." Before being hired to testify in the pelvic mesh litigation, she had never reviewed a pathology slide regarding mesh. *See id*. at 190:10-13. She had removed all or part of one TVT device, but she had never examined Prolift or any other mesh used to treat pelvic organ prolapse. *See id.* at 177:5-17. She had never reviewed the instructions for use for Prolift. *See id.* at 178:17-2279. Now that she has done these things solely in her role as a hired witness, Dr. Weber asks the Court to deem her an expert in all of these subjects.

[1] Dr. Weber does consult with a medical journal for compensation, but this constitutes less than eight hours per month. *See* Ex. B, Weber 11/5/12 Dep. at 14:14-15:7.

B. Dr. Weber's Opinions.

Dr. Weber offers a dizzying array of opinions in her 285-page single-spaced expert report. *See* Ex. E, General Report of Anne Weber, M.D. ("Weber Report"). Dr. Weber's tome covers a wide array of subjects, from the older surgeries to treat pelvic organ prolapse (*i.e.*, the ones that Dr. Weber performed before quitting the practice of medicine in 2005), to Ethicon's development of the Prolift device, to the Prolift procedure, to Dr. Weber's opinions about what Ethicon supposedly "knew" about the potential risks of Prolift at the time of launch.

The actual "opinions" Dr. Weber seeks to offer are difficult to separate from the other information in the expert report, as Dr. Weber provides no identification of her primary opinions, no summary of opinions, and no table of contents. But as far as Ethicon can tell, Dr. Weber's primary opinions appear to be: (1) that Prolift is poorly designed, (2) that Prolift was inadequately studied by Ethicon, (3) that the risks of the Prolift outweigh its benefits, and (4) that Ethicon violated its own credo. *See* Overview, Weber Report, p. 5. Each of these opinions is inadmissible.

III. ARGUMENT

A. Legal standard for admissibility of expert testimony.

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014); *see also* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579, 589 (1993). Applying those standards here, all of Dr. Weber's opinions should be excluded.

B. Dr. Weber's testimony should be excluded in the entirety because she is not qualified to offer the opinions in her expert report.

Dr. Weber's testimony should be excluded in the entirety because she is not qualified to offer opinions regarding the Prolift device.

Dr. Weber's relevant training and experience is as a gynecologist more than a decade ago. She has never used the Prolift device and ceased performing surgeries before the device was even on the market. Ethicon does not contend that clinical experience with a specific device is necessarily required in order for an expert to have an opinion about it. But here, the Court is confronted with the unique situation where the expert—though a practicing gynecologist a decade ago—has garnered her purported expertise in her role as an expert witness.

As this Court has held, "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion." *See Tyree v. Boston Scientific Corp.*, 2014 WL 5486694 (S.D. W. Va. Oct. 29, 2014). But it is a relevant consideration in applying *Daubert*. *See id.*; *see also Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998) ("Another significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying."). The Court still must independently examine whether the expert's testimony is admissible under *Daubert* and Fed. R. Evid. 702.

Federal Rule of Evidence 702 requires that the expert be "qualified . . . by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Weber's knowledge, education, and experience provide her some background knowledge about the conditions Prolift is designed to treat, but it does not make her an expert on the Prolift device or on Ethicon's internal standards and processes, as she claims to be.

As described above, Dr. Weber stopped practicing medicine more than 10 years ago and has not been licensed to practice since 2007. *See* Ex. B, Weber 11/5/12 Dep. at 28:4-6, 146:14-20. She has not performed surgery of any type since 2004—the year before Ethicon launched Prolift. *See id.* at 27:24-28:3. Accordingly, she has had *no* experience implanting the Prolift,

removing the Prolift, or treating complications related to the Prolift. In fact, her only experience treating mesh complications at all was with a different device, and even then she only treated "less than five" patients. *Id.* at 187:12-17. Since surrendering her medical license, Dr. Weber has not attended any continuing medical education courses, and has not participated in any professional education regarding Prolift or any other pelvic mesh products. *See id.* at 146:21-23, 175:14-17, 177:1-4. Nor did she discuss the Prolift device with any surgeons who actually use it. *See id.* at 276:8-13.

Dr. Weber has arrived at her opinions about the Prolift and the internal Ethicon standards she seeks to apply by reading articles and Ethicon's internal documents in her role as an expert witness. But "a person does not become an expert in an area outside of [her] regular field merely by 'reading up' for the specific purpose of testifying." *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2005 WL 1868046, at *12 (N.D. Ohio Aug. 8, 2005); *see also Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1478 (D.V.I. 1994) (witnesses educated in pediatric pathology, pharmacology, and toxicology were not qualified to testify regarding cause of birth defects merely because he reviewed selected literature on the subject for purposes of litigation); *Smith v. Rasmussen*, 57 F. Supp. 2d 736, 766-67 (N.D. Iowa 1999) (holding that expert's literature review "is an insufficient basis or methodology on which to render a reliable expert opinion" and confirming that "[c]ourts are suspicious of purported expertise premised solely or primarily on a literature review"), *aff'd in part, rev'd in part*, 249 F.3d 755 (8th Cir. 2001); *see also Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

Because she is not qualified to offer any of her primary opinions about the Prolift device,

Dr. Weber's testimony should be excluded in its entirety. Dr. Weber's lack of qualifications as to certain specific opinions is discussed in further detail below.

C. Dr. Weber's opinions are inadmissible.

1. Dr. Weber's opinions about biomaterials or the Prolift design should be excluded.

Dr. Weber opines that the Prolift is "poorly designed" and offers a number of opinions regarding such design and biomaterials characteristics as pore size, weight, effective porosity, degradation, and foreign body reaction. *See, e.g.*, Ex. E, Weber Report at 9-10, 51, 98-102, 284. These opinions should be excluded because of Dr. Weber's lack of qualifications and because she has not applied reliable methodology. She has done no testing and cannot support any of these opinions with testing by others that would establish that there is a safer alternative mesh design that would be equally effective in treating pelvic organ prolapse. Dr. Weber lacks "knowledge, skill, experience, training, or education" as to product design or biomaterials as required by Federal Rule of Evidence 702. Fed. R. Evid. 702.

In other cases, this Court has admitted the biomaterials opinions of a physician who had "years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh." *See Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *9-10 (S.D. W. Va. Apr. 28, 2015) (admitting biomaterials opinions of Dr. Galloway, who had extensive experience performing surgical implants, revision surgeries, and removal procedures).

By contrast, here, in her surgical career, Dr. Weber never implanted or explanted a Prolift. Ex. B, Weber 11/5/12 Dep. at 69:14-16, 185:13-18. And she testified that "my clinical experience in managing mesh complications like erosion is limited." *id.* at 187:6-7. In fact, she has only done a mesh revision surgery on one occasion and only for the TVT device, a sling

mesh device which is made of a different mesh material from the Prolift and treats stress urinary incontinence, not pelvic organ prolapse like Prolift. *See id.* at 187:12-17. Dr. Weber is not a biomedical engineer or a polymer scientist, and she has never studied the physical characteristics of Prolift or any other transvaginal mesh. *Id.* at 191:25-192:2, 190:1-93:15. Dr. Weber admits she has no experience in the development of biomaterials. *See id.* at 192:3-12. There is nothing in Dr. Weber's knowledge, skill, experience, training, or education showing her to be an expert in biomaterials.

Likewise, Dr. Weber is not qualified to testify about Prolift's design. She has never been involved in the design of a medical device or the safety assessment of a medical device. *See id.* at 31:14-18; Ex. D, *Gross* 1/17/13 Trial Tr. at 1307:5-12. *See, e.g., Tyree v. Boston Scientific Corp.*, No. 2:12–cv–08633, 2014 WL 5486694, at *47 (S.D. W. Va. Oct. 29, 2014 (Dr. Blaivas not qualified to opine on product design; his experience removing SUI devices and observing complications during removal did not, alone, render him qualified to opine as to design; nor did his work in developing a different (rectus fascial sling) qualify him as an expert in the design of a medical device); *id.* at *68 (allowing a different urogynecologist to testify about product design where he had "performed sling product design work 'namely, a polytetrafluoroethylene suburethral sling in the 1980s, along with . . . design theory work for AMS'").

Neither are Dr. Weber's design and biomaterials based on reliable foundation. In her Report, Dr. Weber simply states it as a known fact that "polypropylene sutures and mesh are not inert and are subject to degradation over time." Ex. E, Weber Report at 98. Dr. Weber does not account for the contrary studies such as those cited by defense expert Shelby Thames, who is, unlike Dr. Weber, actually an expert in polymer science. *See, e.g.*, Ex. F, Thames Report, pp. 72-85. "[I]f the relevant scientific literature contains evidence tending to refute the expert's

theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005); *see also E.E.O.C. v. Freeman*, 778 F.3d 463, 469 ("courts have consistently excluded expert testimony that 'cherry-picks' relevant data"). For this reason too Dr. Weber's opinions about biomaterials should be excluded.

2. Dr. Weber should not be permitted to testify about Ethicon's pre-market testing or study of Prolift.

One of Dr. Weber's primary opinions is that Ethicon failed to conduct proper pre-launch assessment of the Prolift. *See* Weber Report, pp. 14-20. Dr. Weber is not qualified to offer this opinion, nor does she apply a reliable methodology.

Dr. Weber is without any knowledge, experience, or background to evaluate the appropriate testing for a medical device. *See* Fed. R. Evid. 702. She has never been involved in a pre-market clinical trial of a medical device. *See* Ex. B, Weber 11/5/12 Dep. at 33:4-15, 198:9-13; Ex. D, *Gross* 1/17/13 Trial Tr. at 1307:13-16. As this Court has observed, "[e]xperience as a surgeon alone, . . . does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market." *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *15 (S.D. W. Va. Apr. 28, 2015). Dr. Weber's experience as a surgeon more than a decade ago in no way renders her an expert in the testing a medical device manufacture must undertake before or after placing a product on the market.

Neither is Dr. Weber's opinion regarding pre-market testing supported by reliable methodology. Dr. Weber's opinion is that "[b]ased on the criteria utilized by Ethicon in this assessment process, the assessments were inadequately performed, and the resulting conclusion that the Prolift could be marketed as a safe and effective medical device system was incorrect."

Weber Report at 14. She bases this opinion on her own personal "analysis, from a medical perspective" of Ethicon's internal analysis. *Id*. Dr. Weber's own personal opinion is not a valid basis for expert testimony. As noted, she has no objective, verifiable source on which she relies in opining about the need for additional pre-market testing of Prolift other than her professional opinion. This Court excluded Dr. Pence's similar *ipse dixit* opinions about the need for pre-market testing "in her professional opinion" in *Lewis v. Ethicon*, 2014 WL 186872 (S.D. W. Va. Jan. 14, 2014).

This opinion also lacks fit. The jury's task will not be to determine whether the Prolift met Ethicon's internal standards. Ethicon's internal standards are not the legal standard by which the jury will determine liability. *See* Restatement (Third) of Torts: Phys. & Emot. Harm. § 13 cmt. f (2010) (evidence of internal standards "does not set a higher standard of care for the actor"); *McHugh v. Jackson*, 2010 U.S. Dist. LEXIS 18827 at *6 n.4 (D. N.J. March 2, 2010) ("standard of care is not generally measured by provisions in internal guidelines…"); 57A Am. Jur. 2d *Negligence* §174 (as a 'general rule the internal procedures of the private organization do not set the standard of care"). Rather, the jury will be tasked with deciding whether the Prolift is defective or whether its warnings were adequate under state law, not under Ethicon's internal standards.

3. Dr. Weber's testimony about the Johnson & Johnson Credo should be excluded.

Dr. Weber opines that "Ethicon violated its own credo" by marketing the Prolift. Ex. E, Weber Report, p. 5. The Johnson & Johnson Credo is the company's internal standard which provides that its "first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services."

This testimony is irrelevant and misleading because, as noted above, neither Ethicon's nor Johnson & Johnson's internal standards are the legal standard by which the jury will determine liability. *See* Restatement (Third) of Torts: Phys. & Emot. Harm. § 13 cmt. f (2010) ; *McHugh*, 2010 U.S. Dist. LEXIS 18827 at *6. The question for the jury is whether Ethicon violated the standard of care imposed by law, not whether it failed to adhere to an internal credo. Any testimony by Dr. Weber that Ethicon violated the Credo is therefore irrelevant and misleading. *See* Fed. R. Evid. 401, 403.

Further, Dr. Weber is not an expert about the Johnson & Johnson Credo. Dr. Weber is a former practicing physician. She is not offered as an expert in Ethicon or Johnson & Johnson's internal policies. She therefore lacks qualifications to testify about the Johnson & Johnson Credo. *See* Fed. R. Evid. 702.

4. Dr. Weber should not be permitted to opine about what Ethicon knew.

Throughout her Report, Dr. Weber improperly posits that Ethicon "knew" something based on her review of company documents. For instance, portions of her report are titled "Ethicon Knew of All the Risks of the Prolift Prior to Marketing the Prolift" (Report at 49-51) and "Ethicon's Knowledge of the Risks of the Prolift, Internal Documents" (Report at 212-234), an entire section devoted to quoting and summarizing internal documents in order for Dr. Weber to opine about what Ethicon "knew."

Dr. Weber's repeated assertions as to what Defendants "knew" or were "aware of" at various times are improper expert testimony. Dr. Weber is not a clairvoyant. Her expert opinion about what Ethicon "knew" is derived from reading company documents. But the jury is equally capable of examining the evidence entered at trial and determining the company's knowledge. This Court has disapproved of the "use [of] experts to usurp the jury's fact-finding function to

determine Ethicon's state of mind, or whether Ethicon acted reasonably." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 702 (S.D. W. Va. 2014); *Lewis v. Ethicon, Inc.*, Case. No. 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014).

It is well within the average juror's ability to consider the evidence and determine what Ethicon knew and when and to determine why Ethicon acted as it did. *See Persinger v. Norfolk & W. Ry. Co.*, 920 F.2d 1185, 1188 (4th Cir. 1990) (affirming exclusion of expert's testimony where "[w]hen stripped of its technical gloss . . . [the] testimony did no more than state the obvious"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, the Court should preclude Dr. Weber from opining about Ethicon's purported knowledge, motives, or state of mind.

5. Dr. Weber should not be permitted to offer critique of the informed consent process for study participants.

In her report, Dr. Weber opines that Ethicon "design and performed a scientifically invalid study with . . . unethical study participant informed consent documents." Weber Report at 91. She claims that there should have been "an extensive informed consent process designed to clearly notify participants that the use of the Prolift Systems was purely experimental, that the safety and effectiveness could not be reliably stated (hence, the need for clinical study), and that significant, life-altering complications could result, which could be untreatable." *Id*. at 84. This opinion is unreliable, irrelevant, unduly prejudicial and should be excluded.

Dr. Weber is not an expert in ethics, and even if she were, any opinions about an ethical violation are irrelevant to the jury's determination of liability here. *See In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004) ("While the defendants may be liable in

the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits."); *In re Diet Drugs Prod. Liab. Litig.*, 2001 WL 454586, at *9 (E.D. Pa. Feb.1, 2001) ("Dr. La Puma's expertise and experience in clinical medical ethics are, at best, only marginally relevant to AHP's conduct in the manufacturing and marketing of diet drugs"); *Lewis*, 2014 U.S. Dist. LEXIS 15351, *2566 ("matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury."). Dr. Weber's opinion about lack of informed consent for study participants is nothing more than an opinion that Ethicon violated some unspecified ethical duty. These opinions are irrelevant and unduly prejudicial and should be excluded. *See* Fed. R. Evid. 401, 403, 702.

6. Dr. Weber should not be permitted to offer critique of Ethicon's handling of issue reports.

In her report, Dr. Weber opines that certain issue reports should have been reported to the FDA but were not. *See* Weber Report at 90-91, 263-270. This improper opinion should be excluded.

First, Dr. Weber is not an expert in FDA regulations, and therefore lacks the expertise to determine whether an issue report meets the FDA's reporting standards.

Further, evidence concerning whether or not Ethicon reported certain adverse events to the FDA is irrelevant and not helpful to the jury. The improper failure to report an adverse event to the FDA is nothing but a FDCA violation and has no bearing on liability here under state law.

For this reason, among others, this Court has repeatedly excluded such opinions. In *Lewis v. Ethicon*, for example, the Court held that Dr. Pence's opinions about Ethicon's alleged failure to submit medical device reports to the FDA were inadmissible because "whether Ethicon . . . failed to furnish information to the FDA are not facts in issue in this case under Federal Rule

of Evidence 702." 2014 U.S. Dist. LEXIS 15351 at *2604; *see also United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

Dr. Weber's opinion should be excluded.

7. Dr. Weber should be barred from offering opinions about improper selection of physicians for training.

Dr. Weber opines that Ethicon improperly selected physicians for training on the Prolift, stating in her report that "Ethicon compromised patient safety by failing to ensure a high skill level for all trainees" and that "[t]he significance of this issue cannot be overstated." Weber Report at 80-81.

First, these opinions are simply irrelevant if Plaintiffs are not able to link their alleged injuries to their implanting physicians' purported lack of skill. If the physicians performed the surgery correctly, then it is immaterial whether they were skilled enough according to Dr. Weber to be trained to perform the surgery in the first place. *See* Fed. R. Evid. 402, 403, 702.

Moreover, the entire premise underlying Dr. Weber's opinion—*i.e.*, that Ethicon is somehow responsible for "selecting" a surgeon—is simply wrong. In the Prolift IFU, Ethicon recommended training and advised that it was available. *See* Ex. G, Prolift IFU at 2 ("training on the use of the [Prolift] is recommended and available"). But Ethicon does not control any surgeon's decision to seek that training, nor does Ethicon control who can implant the device. Rather, as Dr. Weber herself acknowledged, hospitals typically are responsible for credentialing surgeons and specifying what procedures a particular surgeon may or may not perform. *See* Ex. H, Weber 9/1/15 Dep. at 123:17-23. Further, surgeons do not require training by or permission from Ethicon before using the Prolift device.

Because Ethicon cannot control who ultimately uses the device, Ethicon cannot be held

liable for "inappropriately selecting" a particular surgeon for training on the device. *See, e.g.*, *Sons v. Medtronic Inc.*, No. 6:112-2579, 2013 U.S. Dist. LEXIS 6166 (W.D. La. Jan. 14, 2013) (rejecting plaintiff's failure to train claims and reasoning that "[i]t is well established that a medical device manufacturer is not responsible for the practice of medicine").

This opinion is therefore unreliable, irrelevant, and should be excluded.

8. Dr. Weber should be prohibited from offering summaries of documents and evidence.

In her Report, Dr. Weber waxes on for dozens of pages quoting and summarizing various internal company documents, deposition testimony, and other materials. *See* Weber Report at 165-187 (summarizing emails and deposition concerning Ethicon's input on Altman manuscript). This narrative summary of the evidence as seen through her eyes is more akin to closing argument and is not proper expert testimony, as it is not offered to provide the basis for Dr. Weber's expert testimony. *Cf. Cisson v. C.R. Bard, Inc*, 2013 U.S. Dist. LEXIS 78061, *139 (S.D. W. Va. June 4, 2013) (permitting experts' factual narrative only "to the extent that they may present the bases for their expert opinions").

"[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence." *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005); *see also In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (holding regulatory expert "will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence"); *In re Rezulin*, 309 F. Supp. 2d at 546 (rejecting portion of expert report presenting history of Rezulin for no purpose but to "provid[e] an historical commentary of what happened"); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the

testimony of an expert witness").

Dr. Weber's personal and subjective interpretation and summarization of her subjective views about these materials is not helpful to the jury under Rule 702 and should be excluded.

9. Dr. Weber should be prohibited from using unscientific, inflammatory language in her testimony.

Flowing from Dr. Weber's improper opinion that Ethicon improperly failed to conduct premarket testing is the improper and inflammatory opinion that the women who subsequently were implanted with the Prolift were "test subjects" or "guinea pigs." Weber Report at 5 (faulting Ethicon for "marketing the Prolift to be permanently implanted in women who were unaware that they were no more than test subjects"); *id*. at 84 ("Ethicon's failure to conduct rigorous, long-term clinical study of the Prolift Systems before marketing the product was demonstrates a complete disregard for the health of the women who unknowingly acted as experimental guinea pigs").

This improper characterization should be excluded because it is based on Dr. Weber's unreliable opinion that Ethicon failed to conduct appropriate premarket testing. In addition, the characterization is improper and inflammatory and should be excluded under Fed. R. Evid. 403. Characterizing patients as "guinea pigs" or "test subjects" is not a scientific opinion. It is an inflammatory characterization calculated to provoke sympathy and anger from the jury, and it should not be permitted. *See* Fed. R. Evid. 403; *Hogan v. Novartis Pharms. Corp.*, 2011 U.S. Dist. LEXIS 43800 (E.D.N.Y. Apr. 23, 2011) (excluding testimony where "plaintiff is attempting to use an expert witness to make her closing argument rather than relate scientific conclusions"); *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1233 (5th Cir. 1986) (noting that "the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument").

Further, in her report, Dr. Weber states that "[a]n epidemic of Prolift mesh-related complications is already occurring and will only worsen with time. Truly, this is a 'ticking time bomb' . . . ." Weber Report at 233. Dr. Weber is not an epidemiologist and applies no reliable methodology to determine there is truly an epidemic in the use of the scientific term. *See* Centers for Disease Control, PRINCIPLES OF EPIDEMIOLOGY: GLOSSARY (defining "epidemic" as "the occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a particular period").[2] Dr. Weber's use of hyperbolic, unscientific terms such as "epidemic" and "ticking time bomb" is intended to inflame the jury, and is particularly inappropriate from a witness wearing the mantle of an expert.

Accordingly, if permitted to testify at all, Dr. Weber should be prohibited from using such terms as "guinea pig," "test subjects," "epidemic," or "ticking time bomb."

IV. CONCLUSION

For these reasons, Ethicon respectfully requests that Dr. Weber's testimony be excluded in its entirety.

Respectfully submitted,

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[2] Available at http://www.cdc.gov/OPHSS/CSELS/DSEPD/SS1978/Glossary.html#E (last accessed Apr. 11, 2016).

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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